

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Gary K. Michelson, M.D.)
Serial No.: (Cont. of 08/480,684)) Group Art Unit: (3764)
Filed: October 15, 2003)
For: METHOD FOR FORMING)
THROUGH A GUARD AN) Examiner: (M. Brown)
IMPLANTATION SPACE IN THE)
HUMAN SPINE)

Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicant brings to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed concurrently with the above-referenced application.

Copies of the following listed documents are attached:

4,332,036	4,936,848	WO 88/03781
4,657,550	EP 0 268 115	
4,763,644	EP 0 307 241	
4,904,260	DE 26 21 384	
4,904,261	WO 86/03666	

Cloward, Ralph B.; The Treatment of Ruptured Lumbar Intervertebral Discs by Vertebral Body Fusion; J Neurosurg. 10; pp. 154-167; 1953;

White, Arthur H.; Lumbar Spine Surgery: Some Opinions of General Orthopedists and Superspecialists; pp. 11-15; 27; 30; 35-45; 265-268; 1987;

North American Spine Society Second Annual Meeting, June 25-28, 1987

Arnold, David M.; State of the Art Reviews: Pedicle Fixation of the Lumbar Spine; pp. 176-200, Hanley & Belfus, Inc., 1992.

Morscher, E. et al.; The Anterior Plating of the Cervical Spine with the Titanium Hollow Screw System; Surgeon 57; 702-707; 1986

Copies of the remaining listed documents were previously cited in a prior application, Serial No. 08/480,684, filed June 7, 1995, upon which applicant relies for the benefits provided in 35 U.S.C. § 120.

Please note that ES 283078 is related to U.S. Patent No. 4,877,020; EP 0268115 is related to U.S. Patent No. 4,820,305; DE 26 21 384 is related to U.S. Patent No. 4,177,524; and GB 1291470 is related to DE 1961531.

The present application is a continuation application of Serial No. 08/480,684, filed June 7, 1995. The '684 application is a divisional application of Serial No. 07/968,240, now U.S. Patent No. 5,741,253, which is a continuation of application Serial No. 07/698,674, now abandoned, which is a divisional application of Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Applicant brings to the Examiner's attention that the '247 patent was the subject of litigation in the United States District Court for the Central District of California, Western Division, Civil Action No. 95-0258RG, hereinafter referred to as Litigation 1. The claims of the '247 patent are directed to a fusion implant.

The '253 patent was the subject of litigation in the United States District Court for the Western District of Tennessee, Civil Action No. 98-2369GA (JSG), hereinafter referred to as Litigation 2. The '253 patent was also the subject of litigation in the United States District Court for the Western District of Tennessee, Western Division, Case No. 99-2656GV, hereinafter referred to as Litigation 3 ("Lit. 3"). The claims of the

'253 patent are generally directed to a method for preparing adjacent vertebrae to receive an implant.

U.S. Patent No. 5,484,437 (a continuation in part of the '253 patent) and U.S. Patent No. 6,096,038 (a divisional of the '437 patent) were also the subject of litigation in Litigation 3. The claims of the '437 patent are generally directed to a method for inserting an implant. The claims of the '038 patent are generally directed to instruments used for preparing adjacent vertebrae to receive an implant and/or inserting an implant.

In Litigations 1-3, the defendants asserted that various references were pertinent to the issue of validity of the '247 patent, the '253 patent, the '437 patent, and the '038 patent under 35 U.S.C. §§ 102 and 103. Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by defendants in Litigation 1 as being allegedly pertinent to the '247 patent by the designation "Lit. 1." References identified by the defendants in Litigation 2 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 2." References identified by the defendants in Litigation 3 as being allegedly pertinent to the '437 patent are identified by the designation "Lit. 3a." References identified by defendants in Litigation 3 as being allegedly pertinent to the '253 patent are identified by the designation "Lit. 3b." References identified by defendants in Litigation 3 as being allegedly pertinent to the '038 patent are identified by the designation "Lit. 3c."

The defendants in Litigation 3 also raised allegations of inequitable conduct in relation to the procurement of:

(1) the '253 patent for failing to (a) highlight U.S. Patent No. 4,570,624 to Wu, (b) disclose litigation related to the '247 patent, and (c) disclose EP 0077159 to Atkins, an

article written by Jose Vich ("Anterior cervical interbody fusion with threaded cylindrical bone," *Neurosurg* 63: 750-753, 1985), and manuals by Muller, M.E. ("Manual of Internal Fixation: Techniques Recommended by the AO Group;" Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979), Hierholzer, G. ("Manual on the AO/ASIF Tubular External Fixator;" pp. 85-91; Springer-Verlag; 1985), and Heim, Urs ("Small Fragment Set Manual: Technique Recommended by the ASIF-Group;" pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974);

(2) the '437 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) disclose U.S. Patent No. 2,842,131 to Smith, U.S. Patent No. 4,142,517 to Stavropoulos et al., U.S. Patent No. 4,677,883 to Lee, U.S. Patent No. 4,830,000 to Shutt, U.S. Patent No. 4,878,915 to Brantigan, U.S. Patent No. 4,943,291 to Tanguy, U.S. Patent No. 4,961,740 to Ray et al., and U.S. Patent No. 5,055,104 to Ray; and

(3) the '038 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) filing an allegedly misleading Rule 131 declaration.

Litigations 1-3 are no longer pending. The jury in Litigation 2 found all asserted claims of the '253 patent valid in view of the art cited by the defendant. Litigations 1-3 were settled with the defendants in each litigation retracting their assertions of invalidity and inequitable conduct. Discovery documents relating to the aforementioned litigations are available upon request.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: October 15, 2003

By: 

Amedeo F. Ferraro

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Substitute for FORM PTO-1449	Attorney Docket Number 102.0001-14000	Customer No. 22882
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant Gary K. Michelson, M.D.	Application Number (Cont. of 08/480,684)
(Use several sheets if necessary) Sheet <u>1</u> of <u>4</u>	Filing Date October 15, 2003	Group Art Unit (3764)
Examiner (M. Brown)		

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	D 257511	Nov-80	Zahn			
	D 260525	Sep-81	Lassiter			
Lit. 1	Re. 31,865	Apr-85	Roux			
	2,243,718	May-41	Moreira			
	2,537,070	Jan-51	Longfellow			
	2,543,780	Mar-51	Hipps et al.			
Lit. 2	3,128,768	Apr-64	Geistauts			
Lit. 1	3,298,372	Jan-67	Feinberg et al.			
	3,426,364	Feb-69	Lumb			
Lit. 2	3,486,505	Dec-69	Morrison			
Lit. 1	3,604,487	Sep-71	Gilbert			
Lit. 3b	3,719,186	Mar-73	Merig, jr.			
Lit. 2	3,848,601	Nov-74	Ma et al.			
	3,867,728	Feb-75	Stubstad et al.			
Lit. 2	3,875,595	Apr-75	Froning			
Lit. 2	3,892,232	Jul-75	Neufeld			
Lit. 1	3,905,047	Sep-75	Long			
Lit. 1	4,016,651	Apr-77	Kawahara et al.			
	4,051,905	Oct-77	Kleine			
	4,059,115	Nov-77	Jumashev et al.			
	4,070,514	Jan-80	Entherly et al.			
Lit. 1	4,086,701	May-78	Kawahara et al.			
Lit. 1	4,124,026	Nov-78	Berner et al.			
Lit. 1	4,175,555	Nov-79	Herbert			
Lit. 1	4,177,524	Dec-79	Grell et al.			
	4,181,457	Jan-80	Holmes			
Lit. 1	4,259,072	Mar-81	Hirabayashi et al.			
Lit. 1	4,262,369	Apr-81	Roux			
	4,289,123	Sep-81	Dunn			

Lit. 1	4,293,962	Oct-81	Fuson			
	4,309,777	Jan-82	Patil			
Lit. 1	4,328,593	May-82	Sutter et al.			
	4,332,036	Jun-82	Sutter et al.			
	4,341,206	Jul-82	Perrett et al.			
Lit. 1 & 3c	4,349,921	Sep-82	Kuntz			
Lit. 1	4,356,572	Nov-82	Guillemin et al.			
	4,401,112	Aug-83	Rezaian			
	4,423,721	Jan-84	Otte et al.			
Lit. 1	4,484,570	Nov-84	Sutter et al.			
Lit. 1 & 2	4,501,269	Feb-85	Bagby			
Lit. 2	4,545,374	Oct-85	Jacobson			
	4,553,273	Nov-85	Wu			
	4,554,914	Nov-85	Kapp et al.			
Lit. 2, 3b, & 3c	4,570,624	Feb-86	Wu			
	4,599,086	Jul-86	Doty			
	4,636,217	Jan-87	Ogilvie et al.			
Lit. 1	4,653,486	Mar-87	Coker			
	4,657,550	Apr-87	Daher			
	4,664,567	May-87	Edwards			
	4,710,075	Dec-87	Davison			
Lit. 1	4,713,004	Dec-87	Linkow et al.			
Lit. 3c	4,714,469	Dec-87	Kenna			
	4,736,738	Apr-88	Lipovesek et al.			
Lit. 1 & 2	4,743,256	May-88	Brantigan			
	4,743,260	May-88	Burton			
	4,763,644	Aug-88	Webb			
	4,790,303	Dec-98	Steffee			
	4,805,602	Feb-89	Puno et al.			
	4,820,305	Apr-89	Harms et al.			
Lit. 1 & 2	4,834,757	May-89	Brantigan			
Lit. 2	4,848,327	Jul-89	Perdue			
Lit. 2	4,863,476	Sep-89	Shepperd			
	4,863,477	Sep-89	Monson			
Lit. 1	4,877,020	Oct-89	Vich			
Lit. 1 & 2	4,878,915	Nov-89	Brantigan			
	4,904,260	Feb-90	Ray et al.			
	4,904,261	Feb-90	Dove et al.			

	4,936,848	Jun-90	Bagby			
	4,955,908	Sep-90	Frey et al.			
	5,015,247	May-91	Michelson			
Lit. 1	5,084,050	Jan-92	Draenert			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION (YES/NO)
Lit. 2, 3a, 3b, & 3c	EP 0 077 159	04/1983	Europe			N/A
	EP 0 260 044	3/1988	Europe			N/A
	EP 0 268 115	4/1989	Europe			US Equivalent 4,820,305
	EP 0 307241	3/1989	Europe			N/A
	FR 2581336	11/1986	France			Abstract Only
Lit. 1	DE 1961531	07/1970	Germany			UK Equivalent GB 1291470
	DE 26 21 384	11/1977	Germany			US Equivalent 4,177,524
	DE 31 01 333	12/1981	Germany			Abstract Only
	DE 31 32 520	6/1982	Germany			Abstract Only
Lit. 1	DE 35 05 567 A1	06/1986	Germany			Abstract Only
	GB 1291470	10/1972	G. Britain			N/A
Lit. 1	ES 283078	05/1985	Spain			US Equivalent 4,877,020
	WO 86/03666	7/1986	WIPO			US Equivalent 5,084,050
	WO 88/03781	6/1988	WIPO			Abstract Only

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Lit. 1	Bagby, George W.; Wobbler Syndrome in Horses (the Ataxic Horse); Spokane County Medical Society Bulletin; Spring 1979 .
Lit. 1	Albrektsson, T., et al.; Osseointegrated Titanium Implants; Acta. Orthop. Scand.; Vol. 52:155-170 (1981).
Lit. 1	Raveh, J., et al.; Neue Rekonstruktionsmöglichkeiten des Unterkiefers bei knöchernen Defekten nach Tumorresektionen; Der Chirurg Vol. 53:459-467 (1982).
Lit. 1 & 2	DeBowes, R.M., et al.; Study of Bovine...Steel Baskets; Transactions of the 29th Annual Meeting; Orthopaedic Research Society, Vol. 8, p. 407, March 8-10 (1983).
Lit. 2	Brandt, L., et al.; A Dowel Insert for Anterior Cervical Interbody Fusion; J. Neurosurg. 61:793-794 (October 1984).
Lit. 1	Raveh, J., et al.; Use of the Titanium-coated Hollow Screw and Reconstruction Plate System in Bridging of Lower Jaw Defects; J. Oral Maxillofac Surg. 42:281-294 (1984).
Lit. 1, 2, 3a, & 3b	Otero-Vich, Jose M.; Anterior Cervical Interbody Fusion with Threaded Cylindrical Bone; J. Neurosurg 63:750-753 (November 1985).
Lit. 1	Morscher, E., et al.; Die vordere Verplattung der Halswirbelsäule mit dem Hohlschrauben-Plattensystem aus Titanium, Der Chirurg, Vol. 57, pp. 702-707 (1986) with English Translation.
Lit. 1 & 2	Bagby, G.W.; Basket Implant Facilitates Spinal Fusion; Orthopedics Today, Vol. 7, No. 10, (October 1987).
Lit. 1 & 3a	Butts, M. K., et al.; Biomechanical Analysis of a New Method for Spinal Interbody Fixation; 1987 Symposium, American Society of Mechanical Engineers, "Advances in Bioengineering", Boston, MA (Dec. 13-18, 1987).
Lit. 1	Crawley et al.; A Modified Cloward's Technique for Arthrodesis of the Normal Metacarpophalangeal Joint in the Horse; Veterinary Surgery, Vol. 17, No. 3, pp. 117-127 (1988).

Lit. 1	Raveh, J., et al.; Surgical Procedures for Reconstruction of the Lower Jaw Using the Titanium-Coated Hollow-Screw Reconstruction Plate System: Bridging of Defects; Otolaryngologic Clinics of North America; Vol. 20, No. 3 (August 1987).		
Lit. 2	Goldthwaite, N., et al.; Toward Percutaneous Spine Fusion; Ch. 45; Lumbar Spine Surgery; C.V. Mosby Company, pp. 512-522 (1987).		
Lit. 1 & 2	Bagby, G.W.; Arthrodesis by the Distraction-Compression Method Using a Stainless Steel Implant; Orthopedics, Vol. II, No. 6, pp. 931-34 (June 1987).		
Lit. 1	Itoman, M., et al.; Banked Bone Grafting for Bone Defect Repair--Clinical Evaluation of Bone Union and Graft Incorporation; J. Jpn. Orthop. Assoc. 62:461-469 (1988).		
Lit. 3a & 3c	Cloward, Ralph B.; Surgical Techniques for Lumbar Disc Lesions; Codman; Signature Serial 3.		
Lit. 3c	Cloward, Ralph B.; Ruptured Cervical Intervertebral Discs: Removal of Disc & Osteophytes & Anterior Cervical Interbody Fusion (A.C.I.F.); Codman; Signature Series 4.		
Lit. 3	Cloward, Ralph B.; Recent Advances in Surgery of the Cervical Spine; pp. 285-293; German Society For Neurosurgery: Volume 2 Cervical Spine Operations; Excerpta Medica.		
Lit. 3c	Hutter, Charles George; Spinal Stenosis and Posterior Lumbar Interbody Fusion; pp. 103-114; Clinical Orthopaedics and Related Research; No. 193; The Association of Bone and Joint Surgeons.		
Lit. 3c	Lin, Paul M.; Posterior Lumbar Interbody Fusion; pp. 114-122; Charles C. Thomas; Springfield, Illinois.		
Lit. 3a & 3b	Muller, M.E.; Manual of Internal Fixation: Techniques Recommended by the AO Group; Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979.		
Lit. 3a & 3b	Hierholzer, G.; Manual on the AO/ASIF Tubular External Fixator; pp. 85-91; Springer-Verlag; 1985.		
Lit. 3a & 3b	Heim, Urs; Small Fragment Set Manual: Technique Recommended by the ASIF-Group; pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974.		
Lit. 3c	Harmon, Paul H.; Anterior Excision and Vertebral Body Fusion Operation for Intervertebral Disk Syndromes of the Lower Lumbar Spine: Three- to Five-Year Results in 244 Cases; pp. 107-127; Clinical Orthopaedics and Related Research, No. 26, J.B. Lippincott Company, 1963.		
Lit. 3c	Harmon, Paul H.; A Simplified Surgical Technic for Anterior Lumbar Discectomy and Fusion; Avoidance of Complications; Anatomy of the Retroperitoneal Veins; pp. 130-143; Clinical Orthopaedics and Related Research, No. 37, J.B. Lippincott Company, 1964.		
Lit. 3b	Bullough, Peter G.; Atlas of Spinal Diseases; Figure 5.7; J.B. Lippincott Company; 1988		
	Arnold, David M.; State of the Art Reviews: Pedicle Fixation of the Lumbar Spine; pp. 176-200, Hanley & Belfus, Inc., 1992		
	North American Spine Society Second Annual Meeting, June 25-28, 1987		
	Cloward, Ralph B.; The Treatment of Ruptured Lumbar Intervertebral Discs by Vertebral Body Fusion; J Neurosurg. 10; pp. 154-167; 1953		
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	White, Arthur H.; Lumbar Spine Surgery: Some Opinions of General Orthopedists and Superspecialists; pp. 11-15; 27; 30; 35-45; 265-268; 1987		
<table border="1" style="width: 100%;"> <tr> <td style="width: 35%;">EXAMINER</td> <td style="width: 65%;">DATE CONSIDERED</td> </tr> </table>		EXAMINER	DATE CONSIDERED
EXAMINER	DATE CONSIDERED		
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.			